

Exhibit B

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA**

CHARLESTON DIVISION

IN RE: ETHICON, INC.,
PELVIC REPAIR SYSTEM
PRODUCTS LIABILITY LITIGATION

MDL NO. 2327

THIS DOCUMENT RELATES TO:
ETHICON WAVE 1 CASES

**PLAINTIFFS' MEMORANDUM IN OPPOSITION TO DEFENDANTS' MOTION TO
EXCLUDE GENERAL-CAUSATION TESTIMONY OF DR. NEERAJ KOHLI, M.D.,
M.B.A.**

Plaintiffs respectfully submit this Memorandum of Law in Opposition to Defendants Ethicon, Inc. and Johnson & Johnson's Motion to Exclude General Causation Testimony of Neeraj Kohli, M.D., M.B.A.

Introduction and Qualifications of Dr. Kohli

Dr. Kohli is a board-certified obstetrician gynecologist and fellowship trained urogynecologist with nearly 20 years of clinical experience: (1) he is highly educated and intensively trained in his field of expertise; (2) he has extensive experience with pelvic mesh and its complications; (3) he has authored numerous texts on related subjects; (4) he relies upon dozens of peer-reviewed articles in reaching his conclusions. *See* Def. Exhibit B (Expert Report of Dr. Neeraj Kohli M.D., M.B.A. at § I qualifications). Based on his familiarity with relevant published medical and scientific literature, and his own clinical experiences, Dr. Kohli provides a considerable amount information that is both reliable and helpful to the jury.

Legal Standard of Review

The task of evaluating the reliability of expert testimony is uniquely entrusted to the district court. *Daubert v. Merrell Dow Pharmaceuticals, Inc.* 509 U.S. 579, 589 (1993). District courts enjoy “considerable leeway” in determining the admissibility of expert testimony. *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999). Under Federal Rule of Evidence (“Rule”) 702 if scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education may testify thereto in the form of an opinion or otherwise, provided the testimony (1) is “based upon sufficient facts or data” and (2) is “the product of reliable principles and methods,” (3) which have been reliably applied “to the facts of the case.” See *Tyree*, 2014 WL 5320566 at *2; see also *In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 601 (S.D.W.Va. 2013). A two-part test governs the admissibility of expert testimony (and is combined with Rule 702’s qualification standard). See Rule 702; see also *Tyree*, 2014 WL 5320566 at *2. The evidence is admitted if it “rests on a reliable foundation and is relevant.” *Daubert*, 509 U.S. at 597; see also *Tyree*, 2014 WL 5320566 at *2.

The proponent of expert testimony does not have the burden to “prove” anything. He must, however, “come forward with evidence from which the court can determine that the proffered testimony is properly admissible.” *Maryland Cas. Co. v. Therm-O-Disc, Inc.*, 137 F.3d 780, 783 (4th Cir. 1998); *Tyree*, 2014 WL 5320566 at *2. All *Daubert* demands is that the trial judge serve as a gate keeper and make a “preliminary assessment” of whether the proffered testimony is both reliable and helpful. *Tyree*, 2014 WL 5320566 at *3. In making the required preliminary assessment, the trial court “need not determine that the proffered expert testimony is irrefutable or certainly correct” because, as with all testimony, it will be subject to “testing” by cross-

examination, contrary evidence, and instruction on the burden of proof. See *Id.* (quoting *U.S. v. Moreland*, 437 F.3d 424, 431 (4th Cir. 2006)).

Legal Standard As Applied To Dr. Kohli.

The testimony Dr. Kohli seeks to proffer is in full compliance with the standards set forth in Rule 702, *Daubert* and its progeny. See Rule 702; see also *Daubert*, 509 U.S. at 597 (to be admitted evidence must “rest [] on a reliable foundation and [be] relevant”); *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 262 (4th Cir. 1999) (“[T]he obligation of a district court to determine whether expert testimony is reliable and relevant applies to all expert testimony [i.e. scientific and non-scientific].”). In addition, Plaintiffs aver that applicable law requires that Rule 702 be applied flexibly, see *Daubert*, 509 U.S. at 594, so as to uphold the general framework of the Rules which favors the admissibility of evidence over non-admissibility. *Id.* at 588; see also *Tyree*, 2014 WL 5320566 at *3. In short, “the rejection of expert testimony is the exception rather than the rule.” *U.S. v. Stanley*, No. 12-4572, 2013 WL 3770713 at *1 (4th Cir. July 19, 2013) (internal quotations omitted in the cited quotation.). As such, Plaintiffs respectfully submit that the expert testimony proffered by Dr. Kohli should be admitted as set forth herein and that Ethicon’s Motion should be denied.

Argument

Defendants attack six (6) of Dr. Kohli’s opinions, to include: (1) design defect opinions about the insertion technique related to the TVT-O; (2) opinions related to the complication rate of the TVT-O and the severity of the complications; (3) opinion that clinical studies would have demonstrated “flaws” in the TVT-O; (4) opinion regarding the TVT-O’s appropriateness for certain patient populations; (5) opinions that Ethicon frames to relate to the competency of other physicians; (6) opinions related to Ethicon’s motives, knowledge, and intent. Def. Mot at 1-11.

Plaintiffs address each of Ethicon's claims regarding Dr. Kohli's testimony in turn, and each should be denied.

I. Dr. Kohli's Design Defect Opinions Are Relevant.

a. The Transobturator Insertion Technique Is An Inherent Quality of The TVT-O and is a Design Defect.

Defendants' argument is disingenuous and their attempt to frame Dr. Kohli's opinions as "surgical alternatives" is wrong. The method of inserting the TVT-O is not a "surgical alternative;" rather, it is sold as part of the device kit itself. To be clear, Ethicon designed, marketed, and sold the TVT-O as a procedure, to specifically include the surgical approach through the obturator foramen.¹ Contrast the TVT-O with the TVT, the TVT was designed, marketed and sold for a retropubic surgical approach (behind the pubic bone). The TVT-O and TVT utilize different trocars because different tools are required for retropubic insertion versus transobturator insertion, and they are different. The same mesh is used in both products. Meaning, the insertion approach is an inherent part of the TVT-O, as it is the dispositive difference between the two products.

Further, Defendants argument is contradicted in their own brief. *See* Def. Mot. at 2 (describing Dr. Kohli's opinions as claims that the "TVT-O helical needles make placement 'extremely difficult'"). Dr. Kohli's opinion that the unique design of the TVT-O helical needle makes surgical placement difficult, and injuries more likely, is quite clearly a criticism of the design of the device rather than the accompanying surgical technique. *See* Def. Ex. B. at 32. Indeed, Dr. Kohli's testimony eviscerates any doubt that his opinion concerns the device itself in addition to surgical techniques:

¹ The obturator foramen is the opening created by the ischium and pubis bones of the pelvis through which nerves and blood vessels pass.

Q. Mm-hmm. Now, on page 24 of your report and on Figure 5, you talk about the needles that are used in the TVT-O are far more complex than the TOT.

A. Yes.

Q. Can you just explain what you mean by that?

A. I really wish I had the needles here, but in lieu of that, the traditional needles for a transobuturator fall within two basic categories. One is a flat C needle which is very one dimensional, and it only has a C on it. And then the other is a slightly more 3D helical needle which comes straight out and has a 90 degree curvature to it. Those are both spatially much easier to understand. When we pass needles blindly, we're always taught that you want to try to envision where your needle tip is at all times, and that's a function of the configuration of the needle as well as what its relationship is to the handle. The TVT-O needle – again I wish I had a sample here – if you looked at it, it's a much more complex helix, and as a result, it takes more insight and understanding and potentially experience for a surgeon to know where that tip is.

Q. Okay.

A. And part of the safety profile is if I want to know at all times where my needle tip is, and that was one of the issues I had and one of the issues we discussed in terms of the previous cadaver labs.

Ex. A; Deposition of Dr. Neeraj Kohli, March 21, 2016 at 134:13-135:19.

Accordingly, Ethicon's argument that Dr. Kohli's criticisms of the TVT-O are limited to surgical techniques and not design changes is incorrect and unsupported by the record.

b. Dr. Kohli's Opinions Regarding Safer Surgical Alternatives to the TVT-O Are Admissible.

This Court previously allowed expert testimony as to the superior safety profile of autologous slings over synthetic slings – which necessarily includes testimony as to the surgical procedures of each type of sling. *See, Tyree*, 54 F. Supp. 3d 501, 560 (S.D.W.Va. 2014), as amended (Oct. 29, 2014); *Huskey* Tr. Day 5 at 184:4-191:13, Aug. 28, 2014, attached hereto as Exhibit B; *see also*, Def. Mot at p. 2-4. Yet, despite this previous ruling, Ethicon now urges the

Court to deem Dr. Kohli's opinions regarding the surgical technique for implanting the TVT-O as irrelevant.

Specifically, Ethicon asserts that Dr. Kohli's opinions are inadmissible because they relate to safer surgical procedures as opposed to an alternative design of the TVT-O device. This argument is both incorrect and inapposite. First, Ethicon's contention that Dr. Kohli's opinions are irrelevant to *all Wave 1 cases* because they fail to address a safer alternative design fails to acknowledge that safer alternative design is but one state specific requirement in the Court's larger design defect analysis. For example, in some states a Plaintiff must establish that a manufacturer acted "unreasonably in designing and formulating the product." *DeWitt v. Eveready Battery Co.*, 144 N.C. App. 143, 154, 550 S.E.2d 511, 518 (2001), *aff'd*, 355 N.C. 672, 565 S.E.2d 140 (2002). Dr. Kohli's opinions on the surgical technique *inherent to the TVT-O* and safer alternative techniques go directly to the reasonableness of Ethicon's conduct in designing and formulating the product at issue. These opinions are relevant under Federal Rule of Evidence 401 because they "[have] and tendency to make [the] fact" that Ethicon's TVT-O was unreasonably dangerous – a "fact ... of consequence in determining" whether the TVT-O was defectively designed – more "probable than it would be without the [opinions]." *See* Fed. R. Evid. 401(a)-(b). Here, a jury could conclude that Ethicon's conduct was unreasonable in developing and formulating a product requiring a more dangerous surgical technique with more dangerous properties than the existing alternatives. Such comparisons are similarly relevant in supporting Dr. Kohli's opinion that the risks of the TVT-O outweigh its benefits. *See Winebarger v. Boston Sci. Corp.*, No. 2:13-CV-28892, 2015 WL 1887222, at *7 (S.D.W. Va. Apr. 24, 2015) ("Drawing on his clinical experience and review of relevant literature is a sufficiently reliable method of forming the opinion that *the risks of polypropylene outweigh the benefits.*") (emphasis added). Accordingly, because Dr.

Kohli's opinions are clearly relevant to Ethicon's reasonableness in designing the TVT-O and other factors that are helpful to the jury, Ethicon's argument is meritless.

Similarly, the very case law Ethicon relies upon in support of this position demonstrates that summary judgment, not a *Daubert* motion, is the proper vehicle for its argument. Ethicon does not cite to a single case where a court limited an expert's testimony on a *Daubert* motion and the entirety of the body of law relied upon in support of this point is premised upon determinations at summary judgment. *See* Def. Mot. at 2-5.² While this Court has found expert opinions related to surgical technique unreliable, it has never considered such opinions irrelevant which is the challenge Ethicon asserts here. *See Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 722 (S.D.W. Va. 2014); *Edwards v. Ethicon, Inc.*, No. 2:12-CV-09972, 2014 WL 3361923, at *16 (S.D.W. Va. July 8, 2014); *Winebarger v. Boston Sci. Corp.*, No. 2:13-CV-28892, 2015 WL 1887222, at *7 (S.D.W. Va. Apr. 24, 2015) ("Drawing on his clinical experience and review of relevant literature is a sufficiently reliable method of forming the opinion that the risks of polypropylene outweigh the benefits."). Accordingly, a general *Daubert* Motion is not the proper forum to argue over state specific laws involving individual Wave 1 Plaintiffs; that argument should be in a case specific *Daubert* motion.³

II. Dr. Kohli's Opinions Concerning Complications Are Relevant And Reliable.

Defendants confuse two of Dr. Kohli's opinions; that "[p]olypropylene mesh devices like the TVT-O are associated with complications not seen or seen with much less frequency compared

² *Talley v. Danek Med., Inc.*, 179 F3d 154 (4th Cir. 1999) (affirming summary judgment); *Schmidt v. C.R. Bard, Inc.*, No. 2:11-cv-00978, 2013 WL 3802804 (D. Nev. July 22, 2013) (granting summary judgment where there was no evidence of reasonable alternative design presented); *Bogle v. Sofamor Danek Grp., Inc.*, No. 95-8646, 1999 WL 1132313, at *4 (S.D. Fla. Apr. 9, 1999) (granting summary judgment due to absence of issue of fact on reasonable alternative design); *Sita v. Danek Med., Inc.*, 43 F. Supp. 2d 245, 256 (E.D.N.Y. 1999) (granting summary judgement); *Linsley v. C.R. Bard, Inc.*, No. 98-2007, 2000 WL 343358 (E.D. La. Mar. 30, 2000) (granting summary judgment due to absence of issue of fact on reasonable alternative design)

³ Plaintiffs reserve the right to address these arguments with legal briefing on these issues at the appropriate time or supplement this Response as requested by the Court.

to other non-mesh surgical treatments for SUI” with opinions as to the rates and severity of complications with the TVT-O. Def. Mot. at 5; Def. Ex. B at 26. These opinions, though similar, are distinct and are reliable and relevant for different reasons.

In regard to the former opinion, Defendants’ criticism has been considered and rejected by this Court. Dr. Kohli is largely offering an opinion as to the *existence* of complications inherent to the TVT-O that are not present in non-mesh procedures. Ethicon does not challenge Dr. Kohli’s qualifications to offer this opinion and the studies he cites indicate that the opinion is premised upon reliable supporting data. The lone criticism offered by Ethicon on this opinion is that Dr. Kohli’s reliance materials do not include studies specific to the TVT-O, an argument this Court has rejected repeatedly. *See Winebarger v. Boston Sci. Corp.*, No. 2:13-CV-28892, 2015 WL 1887222, at *34 (S.D.W. Va. Apr. 24, 2015) (“[Expert]’s method is not unreliable just because a direct comparison study does not exist between these treatments. [Expert], by way of his experience with the [mesh] device and his review of the relevant scientific literature, may reliably form an opinion on how these procedures compare.”); *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 720 (S.D.W. Va. 2014) (“Ethicon incorrectly asserts that these studies are irrelevant because they did not review the TVT–O specifically. [Expert]’s opinion is that “mesh complications” are under-reported.”). Accordingly, the Court should not depart from its previous rulings and allow Dr. Kohli to testify as to his opinion that polypropylene mesh devices and the TVT-O are associated with complications not seen in in non-mesh procedures.

Dr. Kohli’s opinions concerning the TVT-O’s unacceptably high complication rate, and opinions as to the frequency of complications seen in polypropylene mesh devices, are similarly reliable. Ethicon criticizes these opinions primarily on the basis that none of the studies cited in Dr. Kohli’s report discuss the TVT-O. However, as mentioned, this court has previously held that

similar criticisms of an expert's failure to rely on articles specific to a device do not necessarily render that expert's methodology unreliable, and that such attacks are better reserved for cross examination at trial. *See Winebarger v. Boston Sci. Corp.*, No. 2:13-CV-28892, 2015 WL 1887222, at *8 (S.D.W. Va. Apr. 24, 2015) ("if there are certain device-specific publications that [expert] failed to review in preparing his expert report, [Defendant] is free to inquire about those publications on cross-examination.").

Similarly, Dr. Kohli's opinions concerning complication rates are supported by his wealth of clinical experience and the multitude of medical literature he cites in support of his opinion. Def. Ex. B at 26. Further, in his deposition, Dr. Kohli testified that his opinion as to the unacceptably high complication rate inherent to the TVT-O was based upon groin pain and dyspareunia which were not present in the native tissue repairs that he had personal experience performing (such as the Burch procedure). Ex. A 153:19-154:6;155:24-156:7. Unlike the opinions at issue in *Huskey*, Dr. Kohli does not offer an opinion as to the specific complication percentage, but instead that the complication rate – in his qualified expert opinion - is unacceptably high in light of his considerable clinical experience, training, and review of the available literature. Dr. Kohli's opinion is admissible.

III. Dr. Kohli's Will Not Opine On Hypothetical Clinical Testing.

Section III of Defendants' Motion to Exclude is Moot as Dr. Kohli will not offer expert opinions on hypothetical clinical testing.

IV. Dr. Kohli's Opinions On The Appropriateness of the TVT-O For Certain Patient Populations Are Reliable and Helpful.

Dr. Kohli's opinion regarding the TVT-O's appropriateness and marketing for certain populations is based upon his personal experience, the medical literature, and Ethicon documents. Def. Ex. B at 33. Ethicon argues that this opinion is "devoid of support," however, this argument

is belied by Dr. Kohli's citations to Ethicon internal documents and considerable literature. *Id.* Moreover, Ethicon's attempt to compare Dr. Kohli's opinions to the opinions' limited in *Edwards* misses the mark. In *Edwards*, Dr. Rosenzweig's opinions were excluded, in part, because they were irrelevant to the one specific plaintiff, as conceded by plaintiff's counsel in that case. *Edwards*, 2014 WL 3361923, at *10 ("As the plaintiffs concede, much of this opinion is not relevant to Ms. Edwards's case and should be excluded."). As a threshold matter, Dr. Kohli is here offered in almost 100 Wave cases, a distinguishable difference from Dr. Rosenzweig's single plaintiff case, that included one set of facts. For that reason alone, the Court should conduct a case-by-case analysis with respect to this proffered opinion, making it inappropriate argument for a general *Daubert* attack. Another distinction from the *Edwards* case is that Dr. Kohli's opinions include specific consideration of how patient anatomy affects different populations. Specifically, Dr. Kohli notes that design and trajectory of the trocars increase the likelihood of undesirable outcomes in specific populations. Def. Ex. B at 35. Because these opinions are based upon an examination of the TVT-O's instrumentation and Dr. Kohli's own experience, they are considerably more helpful to the jury than the opinion offered by Dr. Rosenzweig in *Edwards*.

V. Ethicon's attempt to recast Dr. Kohli's opinions on defective design as opinions regarding the competency of other physicians is unavailing.

Next, Defendants again request an exclusion of Dr. Kohli's defective design opinions by attempting to recast those opinions as relating to the competency of other physicians. Def. Mot. at 8-9. However, this argument is a misunderstanding of Dr. Kohli's opinions and even the excerpts of his expert report offered by Defendants in support of their argument demonstrate why they are wrong.

Defendants cite the *Edwards* opinion as support for their argument. However, in *Edwards*, the Court excluded opinions centered upon Ethicon's trivialization of the TVT-O's surgical learning curve, an opinion drastically different from Dr. Kohli's opinion that the TVT-O product kit is defective. *See* 2014 WL 3361923, at *17 (emphasizing expert's opinion that "*Because the company so trivialized the learning curve and potential complications, many surgeons with inadequate skill and experience perform these surgeries.*" was subject to exclusion); Def. Mot. at 8-9. The opinions excluded in *Edwards* centered upon assertions that Ethicon had marketed the TVT-O procedure as safer to perform than it actually was. Here, the opinions Dr. Kohli offers, and that Defendants attempt to exclude, differ because they center upon the design of the helical needles and instrumentation of the TVT-O kit; namely that the design of the helical needles rendered the TVT-O procedure difficult and dangerous to perform. *Id* at 8. This opinion goes directly to the defective design of the TVT-O rather than Ethicon's subjective intent, and is therefore helpful and reliable. Moreover, Dr. Kohli's opinion --that the instrumentation of the TVT-O makes the procedure more difficult to perform-- is not limited to a sub-group of physicians but is instead applicable to *all physicians* employing the procedure. Because Dr. Kohli's opinion concerns defects in the product itself, rather than Ethicon's marketing actions and subjective intent, his opinion is relevant and admissible.

To the extent Dr. Kohli offers opinions on the competency of other physicians at all, his opinions are squarely rooted in fact and reliable methodology. For example, Dr. Kohli highlights specific portions of the TVT-O IFU to demonstrate that the IFU implied that the TVT-O surgery "could be performed by physicians without skills and knowledge of cystoscopy." Def. Ex. B at 34. Given Dr. Kohli's considerable breadth of experience he is clearly qualified to opine that cystoscopy is "one of the most basic procedures for evaluation and diagnosis of bladder conditions

and complications” and that the IFU indicates that inexperienced surgeons can perform the TVT-O procedure. Accordingly, his opinions on this subject are reliable and helpful to the jury.

VI. Dr. Kohli’s opinions as to Ethicon’s knowledge are reliable and helpful to the jury.

Dr. Kohli will not offer expert opinions on Defendants’ intent, motives or state of mind. However, not all of the examples cited by Defendants fall into that category. Defendants take Dr. Kohli’s opinions and testimony out of context to argue that they are a “narrative review of corporate documents.” *Eghnayem v. Boston Sci. Corp.*, 57 F. Supp. 3d 658, 699 (S.D.W. Va. 2014). In making this argument, Ethicon ignores that Dr. Kohli’s opinions are based largely on his clinical observations or his personal experience, specifically his service as a consultant and educator for medical device companies, including Gynecare, and through this experience and interactions with Ethicon’s own employees. Accordingly, these opinions, which Ethicon seeks to limit, are more than a “narrative review” of corporate documents. Def. Ex B at 3. When the excerpts of Dr. Kohli’s report that Ethicon attempts to limit are read in context there is little doubt that Dr. Kohli’s opinions are reliable and extend further than “narrative review.”

For example, Dr. Kohli’s opinions that the TVT-O’s introduction was “reactionary” or an attempt to “seem more innovative” is based upon his own experience working as “one of the core group of physicians involved in early training” of the TVT-O. Def. Ex. B at 5. Similarly, Dr. Kohli’s criticisms of Ethicon’s motives in introducing the “inside out” surgical technique are based on his personal interactions with Gynecare in addition to his own experiences and observations. Dr. Kohli notes that through his relationship with Gynecare, he voiced specific concerns to Gynecare leadership about this very procedure, only to find that Ethicon’s justification for the TVT-O “inside out procedure” completely contradicted by the introduction of the Prolift. *Id* at 5-6. Thus, Dr. Kohli is not being presented to the jury solely to construct a factual narrative, but

rather to opine upon Ethicon's actions and omissions based upon his considerable expertise and first hand observations of Ethicon's own contradictory behavior. *See In re Fosamax Prods. Liabl. Litig.*, 645 F.Supp.2d 164, 192 (S.D.N.Y. 2009).

CONCLUSION

For the above reasons, Dr. Kohli is qualified to render the opinions he is called to make and those opinions are based on reliable methodology and will assist the jury. Consequently, his opinions are admissible and Ethicon's Motion should be denied.

Dated: May 9, 2016

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CERTIFICATE OF SERVICE

I hereby certify that on May 9, 2016, a true and correct copy of this Response, and exhibits, was served via electronic mail with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to the CM/ECF counsel of record.

/s/ Aimee H. Wagstaff, Esq.